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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/500,511	06/30/2004	Stephen Francis Badylak	3220-72178	6418

23643 7590 09/18/2006
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EXAMINER

CHEN, SHIN LIN

ART UNIT	PAPER NUMBER
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1632

DATE MAILED: 09/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/500,511

Applicant(s)

BADYLAK ET AL.

Examiner

Shin-Lin Chen

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1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 August 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) 1-10 and 16 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11-15, 17 and 18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|----------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>6-30-04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's election of group II, claims 11-15, 17 and 18, in the reply filed on 8-18-06 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

2. Claims 1-10 and 16 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 8-18-06.

Applicants' preliminary amendment filed 6-30-04 has been entered. Claims 1-18 are pending. Claims 11-15, 17 and 18 are under consideration.

Specification

3. The disclosure is objected to because of the following informalities: The term "CLAIMS" on line 1 of page 24 is improper. Changing the term "CLAIMS" on page 24 of the specification to "We claim:" or "What is claimed is:" would be remedial.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 11-15, 17 and 18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 11 depends from non-elected claim 1. It is unclear what is intended in claim 11.
Claims 12-15, 17 and 18 depend from claim 11 but fail to clarify the indefiniteness.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 11-15, 17 and 18 are rejected under 35 U.S.C. 102(e) as being anticipated by Badylak, S., 2002 (US Patent No. 6,379,710 B1, IDS-AG).

The applied reference has a common inventor, Stephen Badylak, with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention “by another,” or by an appropriate showing under 37 CFR 1.131.

Claims 11-15, 17 and 18 are directed to a liver basement membrane graft composition comprising basement membrane of warm-blooded vertebrate liver tissue prepared by the method of claim 1, wherein the liver basement membrane could be fluidized, in gel form, or in powder

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form, and a liver tissue derived composition for supporting the growth of a cell population, said composition comprising said liver basement membrane composition and added nutrient to support the growth of said cell population in vitro, or said composition comprising culture-ware coated with a matrix comprising said liver basement membrane composition.

Badylak teaches a tissue graft composition comprising liver basement membrane prepared by removing the cellular components from liver tissue by treating the liver tissue with a solution comprising an enzyme, such as trypsin or pepsin, and a calcium chelating agent or chaotropic agent such as a mild detergent Triton 100, or with a solution comprising only the chelating agent or chaotropic agent (e.g. abstract, column 3, lines 1-15). The liver tissue slice can be suspended in an agitated solution containing protease, optionally containing a chaotropic agent or a calcium chelating agent in an amount effective to optimize release and separation of cells from the basement membrane without substantial degradation of the membrane matrix (e.g. column 3, lines 16-24). Badylak further teaches that the liver basement membrane can be fluidized or in powder form (e.g. column 3, lines 39-60, column 11, 12), cell growth substrate are formed from fluidized forms of liver basement membrane and the fluidized tissue can be gelled to form solid or semi-solid matrix (e.g. column 8, lines 12-18), and the cell growth substrate can be combined with nutrients, such as minerals, amino acids, sugars, peptides, proteins, glycoproteins that facilitate cellular proliferation and growth factors (e.g. column 8, lines 26-32). Badylak also teaches that “fluidized forms of liver basement membrane can be used to coat culture-ware with a matrix comprising liver basement membrane devoid of source liver tissue endogenous cells. Thus, liver basement membrane can be used as a cell growth substrate in a variety of forms, including a sheet-like configuration, as a gel matrix, as an additive for art-

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recognized cell/tissue culture media, or as coating for culture-ware to provide a more physiologically relevant substrate that support and enhances the proliferation of cells” (e.g. column 7, lines 48-53). Claims 11-15, 17 and 18 are product claims and the recited liver basement membrane composition does not appear any different from the liver basement membrane composition as taught by Badylak. Badylak teaches every limitation recited in the claims. Thus, claims 11-15, 17 and 18 are anticipated by Badylak.

8. Claims 11-15, 17 and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Badylak, S., 1998 (WO 98/25637).

Claims 11-15, 17 and 18 are directed to a liver basement membrane graft composition comprising basement membrane of warm-blooded vertebrate liver tissue prepared by the method of claim 1, wherein the liver basement membrane could be fluidized, in gel form, or in powder form, and a liver tissue derived composition for supporting the growth of a cell population, said composition comprising said liver basement membrane composition and added nutrient to support the growth of said cell population in vitro, or said composition comprising culture-ware coated with a matrix comprising said liver basement membrane composition.

Badylak teaches a tissue graft composition comprising liver basement membrane prepared by removing the cellular components from liver tissue by treating the liver tissue with a solution comprising an enzyme, such as trypsin or pepsin, and a calcium chelating agent or chaotropic agent such as a mild detergent Triton 100, or with a solution comprising only the chelating agent or chaotropic agent (e.g. abstract, p. 3-4). The liver tissue slice can be suspended in an agitated solution containing protease, optionally containing a chaotropic agent or a calcium

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chealating agent in an amount effective to optimize release and separation of cells from the basement membrane without substantial degradation of the membrane matrix (e.g. p. 4).

Badylak further teaches that the liver basement membrane can be fluidized or in powder form (e.g. p. 4-5, 16), cell growth substrate are formed from fluidized forms of liver basement membrane and the fluidized tissue can be gelled to form solid or semi-solid matrix (e.g. p. 11, second paragraph), and the cell growth substrate can be combined with nutrients, such as minerals, amino acids, sugars, peptides, proteins, glycoproteins that facilitate cellular proliferation and growth factors (e.g. p. 11, third paragraph). Badylak also teaches that “fluidized forms of liver basement membrane can be used to coat culture-ware with a matrix comprising liver basement membrane devoid of source liver tissue endogenous cells. Thus, liver basement membrane can be used as a cell growth substrate in a variety of froms, including a sheet-like configuration, as a gel matrix, as an additive for art-recognized cell/tissue culture media, or as coating for culture-ware to provide a more physiologically relevant substrate that support and enhances the proliferation of cells” (e.g. p. 10, second paragraph). Claims 11-15, 17 and 18 are product claims and the recited liver basement membrane composition does not appear any different from the liver basement membrane composition as taught by Badylak. Badylak teaches every limitation recited in the claims. Thus, claims 11-15, 17 and 18 are anticipated by Badylak.

Conclusion

No claim is allowed.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shin-Lin Chen whose telephone number is (571) 272-0726. The examiner can normally be reached on Monday to Friday from 9:30 am to 6 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for this group is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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Shin-Lin Chen, Ph.D.

**SHIN-LIN CHEN
PRIMARY EXAMINER**